



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0756]

Study Design Considerations for Devices Including Digital Health Technologies for Sleep
Disordered Breathing in Adults; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “Study Design Considerations for Devices including Digital Health Technologies for Sleep Disordered Breathing in Adults.” The topic to be discussed is the appropriate design of clinical studies to evaluate devices including digital health technologies intended for the diagnosis, monitoring, or treatment of sleep disordered breathing (SDB) in adults. Study design considerations to be discussed include definitions for SDB conditions, inclusion/exclusion criteria for studies of these conditions, use of SDB assessment technologies, controls, and study endpoints.

DATES: The public workshop will be held on April 16, 2018, from 8 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by April 30, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security

information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 30, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end April 30, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-N-0756 for “Study Design Considerations for Devices including Digital Health Technologies for Sleep Disordered Breathing in Adults; Public Workshop; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The

Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sageev George, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2443, Silver Spring, MD 20993, 301-796-6468, sageev.george@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Over the past several years, FDA has seen a marked increase in premarket submissions for devices intended for both the diagnosis and treatment of SDB. These include novel technologies for in-home assessment, intra-oral appliances, externally worn devices that generate increased upper airway pressures, passive implants, active implantable devices that stimulate the upper airway neuromusculature, and mobile apps for assessing and monitoring sleep. The large variety of technologies often poses different and challenging questions of safety and effectiveness and differing benefit-risk profiles for these devices. We have planned this workshop to bring together device regulators, clinical experts in sleep medicine, patients, and other stakeholders to discuss these challenges and potential solutions. The goal is to expedite innovation in SDB devices including digital health technologies and make sure that patients have timely access to reasonably safe and effective devices. To this end, we are actively seeking input and participation from several professional societies and patient advocacy groups with interests in the field of SDB.

II. Topics for Discussion at the Public Workshop

The topics to be discussed are the appropriate design of clinical studies to evaluate devices and digital health technologies intended for the diagnosis, monitoring, or treatment of SDB in adults. Study design considerations to be discussed include definitions for SDB conditions, inclusion/exclusion criteria for studies of these conditions, use of SDB assessment technologies (e.g., polysomnography, home sleep studies), controls, and study endpoints.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select

this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by April 9, 2018, by 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993-0002, 301-796-5661, email: Susan.Monahan@fda.hhs.gov, no later than April 9, 2018.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the registration web page after April 9, 2018. Organizations are requested to register all participants, but to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available approximately 45 days after the public workshop on the internet at <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

Dated: March 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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